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June 23, 2006

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Application No. 10/563,956  
Filed: January 10, 2006  
Title: Autologous Self-Tolerance Inducing Cells of Monocytic  
Origin and Their Use in Pharmaceutical Preparations  
Applicants: Bernd Karl Friedrich KREMER *et al.*  
Atty. Docket: 18724.009

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office (PTO):

1. an Information Disclosure Statement;
2. a Form PTO-1449 (citing and supplying 41 references); and
3. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any additional fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387 referencing matter number 18724.009. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)

Kristan L. Lansbery (Reg. No. 53,183)

Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Bernd Karl Friedrich KREMER *et al.*

Art Unit: 1645

Appl. No.: 10/563,956

Examiner: To Be Assigned

Filed: January 10, 2006

Confirmation No. 3600

Atty Docket. 18724.009

For: Autologous Self-Tolerance Inducing Cells of Monocytic Origin and Their Use in  
Pharmaceutical Preparations

**Information Disclosure Statement**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to consider the references listed on the attached Form PTO-1449. Copies of the references are submitted herewith

It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**Certification and/or Fee**

Because this Information Disclosure Statement is being submitted prior to issuance of the first action on the merits of the above-captioned application, no certification or fee is required.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)

Kristan L. Lansbery (Reg. No. 53,183)

Date: June 23, 2006

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FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

18724.009

APPLICATION NO.

10/563,956

APPLICANTS

Bernd Karl Friedrich KREMER *et al.*

FILING DATE

January 10, 2006

GROUP

1645

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AAI						
	ABI						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	ACI	WO 98/53048 A	11/1998	WIPO			Yes No
	ADI	WO 00/42856 A1	07/2000	WIPO			Yes No
	AEI	WO 02/40646 A	05/2002	WIPO			Yes No
	AFI	WO 02/097070 A1	12/2002	WIPO			Yes No
	AGI	WO 03/083092 A1	10/2003	WIPO			Yes No
	AHI	WO 04/007701 A1	01/2004	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AII	Acholonu <i>et al.</i> , "The role of bone marrow transplantation in tolerance: organ-specific and cellular grafts", <i>Current Opinion in Organ Transplantation</i> (1999) 4:189-96
	AJI	Cobbold <i>et al.</i> , "Regulatory T cells in the induction and maintenance of peripheral transplantation tolerance", <i>Transplantation Int.</i> (2003) 16:66-75
	AKI	Dey <i>et al.</i> , "Outcomes of recipients of both bone marrow and solid organ transplants", <i>Medicine</i> (1998) 77:355-69
	ALI	Dulbecco <i>et al.</i> , "Plaque formation and isolation of pure lines with poliomyelitis viruses", <i>J. Experimental Medicine</i> (1954) 98:167-82
	AMI	Fändrich <i>et al.</i> , "Preimplantation-stage stem cells induce long-term allogeneic graft acceptance without supplementary host conditioning", <i>Nature Medicine</i> (2002) 8:171-8
	ANI	Fändrich <i>et al.</i> , "Tolerance-Inducing Strategies in Transplantation Surgery-Current Status and Perspectives", <i>Langenbecks Arch Surg</i> , 389:60-66 (2004)

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO.	APPLICATION NO.
		18724.009	10/563,956
		APPLICANTS	
		Bernd Karl Friedrich KREMER <i>et al.</i>	
		FILING DATE	GROUP
		January 10, 2006	1645
	AOI	Gmelig-Meyling <i>et al.</i> , "Simplified procedure for the separation of human T and non-T cells", <i>Vox Sang</i> (1977) 33:5-8	
	API	Griffith <i>et al.</i> , "Chapter 9: Epithelial cell culture: cornea", <i>In: Methods of Tissue Engineering/ed. by Anthony Atala; Robert P. Lanza. - San Diego et al.: Academic Press</i> (2002) 131-40	
	AQI	Hay, "Chapter 4: Cell quantitation and characterization", <i>In: Methods of Tissue Engineering/ed. by Anthony Atala; Robert P. Lanza. - San Diego et al., Academic Press</i> (2002) 55-84	
	ARI	Hori <i>et al.</i> , "Control of regulatory T cell development by the transcription factor <i>Foxp3</i> ", <i>Science</i> (2003) 299:1057-61	
	ASI	International Search Report completed November 13, 2003 in PCT/EP03/07551	
	ATI	International Search Report of PCT/EP2004/000109 mailed August 30, 2004	
	AUI	Khattari <i>et al.</i> , "An essential role for Scurfin in CD4 <sup>+</sup> CD25 <sup>+</sup> T regulatory cells", <i>Nature Immunology</i> (2003) 4:337-42 (April 2003).	
	AVI	Köhler <i>et al.</i> , "Continuous cultures of fused cells secreting antibody of predefined specificity", <i>Nature</i> (1975) 256:495-7	
	AWI	Kurnick, "Chapter 40: Cellular assays", <i>In: Diagnostic Immunopathology/ed. by R.B. Colvin et al. - 2. Ed. - New York: Raven Press</i> (1995) 751-71	
	AXI	Lehmann <i>et al.</i> , "Expression of the integrin $\alpha\text{E}\beta\text{7}$ identifies unique subsets of CD25 <sup>+</sup> as well as CD25 <sup>-</sup> regulatory T cells", <i>Proc. Natl. Acad. Sci. USA</i> (2002) 99:13031-6	
	AYI	Lopez <i>et al.</i> , "Infusion of Large Quantities of Autologous Blood Monocyte-Derived Macrophages in Two Cancer Patients did not Induce Increased Concentration of IL-6, TNF- $\alpha$ , Soluble CD14 and Nitrate in Blood Plasma", <i>Eur. Cytokine Netw.</i> , 5(4):411-414 (1994)	
	AZI	Lucas <i>et al.</i> , "Self-Renewal, Maturation, and Differentiation of the Rat Myelomonocytic Hematopoietic Stem Cell", <i>FASEB Journal</i> , 13(2):263-272 (1999)	

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		January 10, 2006	1645
	AA2	Moore, "Culture of normal human leukocytes", <i>J. American Medical Ass.</i> (1967) 199:87-92	
	AB2	Munn <i>et al.</i> , "Selective Activation-Induced Apoptosis of Peripheral T Cells Imposed by Macrophages", <i>The Journal of Immunology</i> , 156(2):523-532 (1996)	
	AC2	Munn <i>et al.</i> , "Inhibition of T cell proliferation by macrophage tryptophan catabolism", <i>J. Experimental Medicine</i> (1999) 189:1363-72	
	AD2	Nawa <i>et al.</i> , "G-CSF Reduces IFN-Gamma and IL-4 Production by T Cells After Allogeneic Stimulation by Indirectly Modulating Monocyte Function", <i>Bone Marrow Transplantation</i> , 25(10):1035-1040 (2000)	
	AE2	Ono <i>et al.</i> , "Improved technique of heart transplantation in rats", <i>J. Thoracic and Cardiovascular Surgery</i> (1969) 57:225-9	
	AF2	Preffer, "Chapter 39: Flow cytometry", <i>In: Diagnostic Immunopathology/ed. by R.B. Colvin et al. - 2.Ed. - New York: Raven Press (1999) 725-33</i>	
	AG2	Roncarolo <i>et al.</i> , "The Role of Different Subsets of T Regulatory Cells in Controlling Autoimmunity", <i>Current Opinion in Immunology</i> , 12(6):676-683 (2000)	
	AH2	Rutella <i>et al.</i> , "Role for Granulocyte Colony-Stimulating Factor in the Generation of Human T Regulatory Type 1 Cells", <i>Blood</i> , 100(7):2562-2571 (2002)	
	AI2	Shimizu <i>et al.</i> , "Stimulation of CD25 <sup>+</sup> CD4 <sup>+</sup> regulatory T cells through GITR breaks immunological self-tolerance", <i>Nature Immunology</i> (2002) 3:135-142	
	AJ2	Sloand <i>et al.</i> , "Pharmacologic Doses of Granulocyte Colony-Stimulating Factor Affect Cytokine Production by Lymphocytes In Vitro and In Vivo", <i>Blood</i> , 95(7):2269-2274 (2000)	
	AK2	Utz <i>et al.</i> , "Analysis of the T-cell receptor repertoire of human T-cell leukemia virus type 1 (HTLV-1) tax-specific CD8 <sup>+</sup> cytotoxic T lymphocytes from patients with HTLV-1-associated disease: evidence for oligoclonal expansion", <i>J. Virology</i> (1996) 70:843-51	
	AL2	Volpi <i>et al.</i> , "Postgrafting Administration of Granulocyte Colony-Stimulating Factor Impairs Functional Immune Recovery in Recipients of Human Leukocyte Antigen Haplotype-Mismatched Hematopoietic Transplants", <i>Blood</i> , 97(8):2514-2521 (2001)	

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		January 10, 2006	1645
	AM2	Weissman, "Translating Stem and Progenitor Cell Biology to the Clinic: Barriers and Opportunities" <i>Science</i> , 287(5457):1442-1446 (2000)	
	AN2	Wekerle <i>et al.</i> , "Allogeneic bone marrow transplantation with co-stimulatory blockade induces macrochimerism and tolerance without cytoreductive host treatment", <i>Nature Medicine</i> (2000) 6:464-9	
	AO2	Wheeler <i>et al.</i> , "Evolution and etiology of cardiovascular diseases in renal transplant recipients", <i>Transplantation</i> (2000) 70:SS41-5	
	AP2	Wolff, "Hematopoietic cell transplant from volunteer unrelated or partially matched related donors: recent developments", <i>Current Opinion in Organ Transplantation</i> (2000) 5:372-81	
	AQ2	Wood <i>et al.</i> , "Regulatory T cells in transplantation tolerance", <i>Nature Reviews Immunology</i> (2003) 3:199-210	
	AR2		

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